

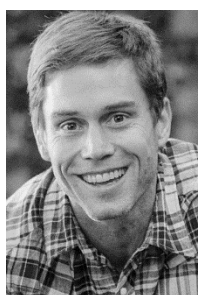
Improving the Implementation of Risk-Based Monitoring Approaches of Clinical Investigations

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Biographies



Jonathan Andrus, Chief Business Officer, leads Clinical Ink's solution management & compliance teams to help sponsors and CROs better leverage eSource, eCOA and ePRO data. With 20+ years of eClinical experience, Mr. Andrus brings extensive expertise developing eClinical services that integrate data and technology to help life science companies optimize study execution. At Clinical Ink, Mr. Andrus is responsible for P&L across Clinical Ink's products and services and he is also focused on building relationships and forging strategic partnerships with sponsors, CROs, regulatory bodies and clinical research professionals. Mr. Andrus joined Clinical Ink from BioClinica where he led the eClinical Solutions Group to develop their current service offerings, including data management, quality management, implementation services and IWRS. Prior to BioClinica, Mr. Andrus worked in pharmaceutical consulting and with CROs focused on quality, data management and validation. An active thought leader, blogger and presenter, Jonathan served as chair of the Society for Clinical Data Management (SCDM) in 2008 and 2013 and currently serves as the society's Treasurer. He is also an active member of DIA (North American Advisory Council and Annual Conference Data/Data Standards Track Chair) and ASQ. He earned his bachelor's and master's degrees from Temple University's College of Liberal Arts and Graduate School of Pharmacy and is a Certified Quality Auditor (CQA) and Certified Clinical Data Manager (CCDM®).



Brian Barnes is a Director of Risk Based Monitoring (RBM) and has been with PPD for 14 years. He has been engaged with RBM for over 7 years and specializes in RBM operationalization for small to large pharma, biopharma, and biotech companies. Brian has presented and published on the topic of RBM within a number of industry meetings, conferences, and journals. Brian resides in Madison, WI with his wife and can often be found riding his bike or adventuring with his tripod boxer.



David Burrow serves as the Director of the Office of Scientific Investigations (OSI), within the U.S. Food and Drug Administration (FDA), Center for Drug Evaluation and Research (CDER), Office of Compliance (OC). In this role, Dr. Burrow leads efforts to shield the American public from unsafe and ineffective drug products. His leadership in the Agency's Bioresearch Monitoring (BIMO) program includes the development and implementation of policies, surveillance activities, and compliance strategies for CDER-regulated products. Additionally, he oversees the enforcement of clinical and non-clinical drug product studies, bioequivalence studies, human subject protections, post-market adverse drug experience reporting requirements, risk evaluation and mitigation strategies, and post marketing requirements. Dr. Burrow's oversight in each of these critical programs supports the overarching goals of the Agency's BIMO program, which include protecting the rights, safety, and welfare of subjects involved in FDA-regulated clinical trials; determining the accuracy and reliability of clinical trial data submitted to FDA in support of research or marketing applications; and assessing compliance with FDA's regulations governing the conduct of clinical trials, including those for informed consent and ethical review. Dr. Burrow has held a variety of leadership positions during his eight years in OSI. In addition to the last four years as the Office Director, he has served as the Deputy Office Director, Policy Staff Director, Associate Director for Policy and Communication, Enforcement Policy Team Leader, and Regulatory Counsel. Before joining the CDER Office of Compliance, Dr. Burrow served two years with the Center for Devices and Radiological Health (CDRH) in their Office of Compliance. Dr. Burrow holds a Doctor of Pharmacy from Duquesne University, and a Juris Doctorate from Widener University School of Law. He is licensed to practice law in the State of Maryland.



Michele Cameron is the Director of Clinical Research for Clearwater Cardiovascular Consultants. CCC is an independent cardiology practice with 22 cardiologist/investigators and has been conducting cardiovascular drug and device studies in both the office & hospital settings for over 25 years. The Site has 12 full time research staff, recruits subjects from a database of 140,000 patients and manages 30-35 studies annually. Michele has been an active member of the Site Solutions Summit and the Society of Clinical Research Sites since 2005 and is currently Chair of the Membership Committee. Her professional background includes Clinical Research Project Manager for GE Medical, Critikon, LLC and Johnson & Johnson, Inc. and working bedside as a cardiovascular intensive care nurse. Michele was raised in Skaneateles, N.Y. and enjoys boating, fishing and attending Tampa Bay sporting events with her family.



Stephanie Clark is a Director in Janssen R&D's Risk Management-Central Monitoring Group, which is dedicated to the implementation of Analytical Risk-Based Monitoring on clinical trials. In this role, Stephanie has contributed to the creation and management of processes, resources, and technology to support the analytical and risk-based model of clinical trial management and monitoring that has now supported more than 170 clinical studies across multiple sectors at Johnson & Johnson (including Pharma, Medical Devices, and Consumer products). She has also participated as a member of the TransCelerate BioPharma Risk-Based Monitoring Initiative. Stephanie has over 15 years of experience in clinical research and drug development. Prior to her ARBM-focus, she worked in clinical trial and site management at Janssen R&D and Centocor R&D, at RPS, Inc., and at ICON in a variety of therapeutic areas, as well as in basic immunological research at Children's Hospital of Philadelphia.



Jacqueline Corrigan-Curay serves as Director of CDER's Office of Medical Policy (OMP). She leads the development, coordination, and implementation of medical policy programs and strategic initiatives. She works collaboratively with other CDER program areas, FDA centers, and stakeholders on enhancing policies to improve drug development and regulatory review processes. OMP is comprised of the Office of Prescription Drug Promotion (OPDP) and the Office of Medical Policy Initiatives (OMPI). OPDP oversees the regulation of prescription drug promotion and advertising. OMPI provides oversight and direction for new and ongoing policy initiatives in broad-based medical and clinical policy areas. Prior to joining FDA, she served as supervisory medical officer with the Immediate Office of the Director, National Heart, Lung and Blood Institute (NHLBI), at National Institute of Health's (NIH) where she focused on developing policies and procedures to enhance the clinical trial enterprise. She also served as the Director of the Office of Biotechnology Activities (OBA), Office of Science Policy at NIH, where she was executive secretary of the NIH Recombinant DNA Advisory Committee. She has held positions as an attending physician with the VA Medical Center, a policy analyst with the Congressional Office of Technology Assessment, and a practicing attorney in Washington, D.C. Dr. Corrigan-Curay earned her law degree from Harvard Law School, her medical degree from University of Maryland School of Medicine, and a bachelor's degree in history of science from Harvard/Radcliffe College in Cambridge, MA. She completed her training in internal medicine at Georgetown University Medical Center, where she also served as a clinical assistant professor of medicine. She continues to practice internal medicine part-time at the Veterans Affairs Medical Center in Washington, D.C.



Gregory Daniel is a Clinical Professor in Duke's Fuqua School of Business and Deputy Director in the Duke-Robert J. Margolis Center for Health Policy at Duke University. Dr. Daniel directs the DC-based office of the Center and leads the Center's pharmaceutical and medical device policy portfolio which includes developing policy and data strategies for improving development and access to innovative pharmaceutical and medical device technologies. This includes post-market evidence development to support increased value, improving regulatory science and drug development tools, optimizing biomedical innovation, and supporting drug and device payment reform.

Dr. Daniel is also a Senior Advisor to the Reagan-Udall Foundation for the FDA and Adjunct Associate Professor in the Division of Pharmaceutical Outcomes and Policy at the UNC Eshelman School of Pharmacy. Previously, he was Managing Director for Evidence Development & Biomedical Innovation in the Center for Health Policy and Fellow in Economic Studies at the Brookings Institution and Vice President, Government and Academic Research at HealthCore (subsidiary of Anthem, Inc). Dr. Daniel's research expertise includes utilizing electronic health data in designing research in health outcomes and pharmacoconomics, comparative effectiveness, and drug safety and pharmacoepidemiology. Dr. Daniel received a PhD in pharmaceutical economics, policy and outcomes from the University of Arizona, as well as an MPH, MS, and BS in Pharmacy all from The Ohio State University.



Mike Henderson is a lifetime learner with a background in statistics. He has a passion for quantifying the patient experience in healthcare through better drug and device evaluation in research, development, clinical, and market settings. He has over a decade of experience in clinical trials research covering drugs, devices and combinations with a focus on inferential methods for patient-reported outcomes, efficient trial design and conduct, and the application of Bayesian methods. Mike has built on this experience in a customer advisory role at SAS for the past 7 years to help life science, care provider, and healthcare companies apply analytical techniques to better understand and predict the impact of care on the patient experience.



Debra Jendrasek has been in the clinical industry for more than 20 years holding various positions within Data Management, Strategic Development and Clinical Operations. She is currently a senior level executive within the CRO / Biotech environment. In her role at Premier Research she is responsible for developing the processes, implementing the technology and building the expertise at Premier to enable and enhance Risk Based Study Execution. Deb's team works to ensure the holistic oversight of clinical site performance in order to proactively direct the monitoring effort. Deb has been a member of the RBM Working Group of the CRO

Forum for the last 3 years.



Alyson Karesh is the Director of the Division of Clinical Trial Quality in the Office of Medical Policy at FDA, where she leads policy development activities that enhance the science and efficiency of clinical trials while promoting clinical trial quality. Dr. Karesh served previously in multiple roles in the Office of New Drugs, Division of Pediatric and Maternal Health, at FDA. Dr. Karesh has presented extensively at FDA-sponsored advisory committee meetings, addressing topics focused on the safety of drug use in the pediatric population. Prior to joining FDA, Dr. Karesh worked as a hospitalist and as a general pediatrician. Dr. Karesh received her undergraduate degree from the University of Virginia and her medical degree from the Medical College of Virginia, and she completed her pediatric internship and residency at Children's Hospital of Pittsburgh.



Anne Lindblad is the President and CEO of Emmes, a global Contract Research Organization founded in 1977 with over 650 staff members serving both Industry and government clients. Dr. Lindblad is a biostatistician with more than 37 years of experience supporting clinical research projects. As the President and CEO of Emmes, Dr. Lindblad is responsible for providing strategic leadership for the company by working with the Board and other management personnel to establish long-range goals, strategies, plans and policies. Dr. Lindblad has supported clinical research throughout her career, serving as Principal Investigator of projects spanning diverse disease areas, including oncology, dialysis, transplantation, ophthalmology, speech and hearing, dentistry, and neurology. She has co-authored numerous publications in each of these areas and has witnessed first-hand the challenges in conducting sound research. From this experience, she has contributed to the literature in such fields as patient-reported outcome development, central statistical monitoring as part of a risk-based monitoring plan, disease classification systems, and barriers to recruiting for clinical trials. Dr. Lindblad has been an NIH reviewer on multiple project applications for NEI, NICHD, NIDCR, NIDDK, NINDS, and NCCAM and has served as a member or chair of several Data and Safety Monitoring Committees for NEI, NIAAA, NIDDK, and NINDS and Industry. She was a member of an Advisory Committee charged with drafting policy to shape the appropriate planning and conduct of intramural studies at NIH. She was elected to the Board of Directors for the Society for Clinical Trials (2003-2006) and served as Program Chair (2002), as an Officer (2006-2014), and as President (2012-2013). Dr. Lindblad was selected to serve on NIH's National Advisory Dental and Craniofacial Research Council from 2004 through 2008. She has taught courses in best practices in clinical trial design and conduct for ophthalmologists, neurologists, and immunologists. Dr. Lindblad has a PhD in Statistics from George Washington University, a Masters degree in Biostatistics from the Medical College of Virginia, VA Commonwealth University, and a Bachelor of Science degree in Statistics from Hollins College.



Sharon Love worked for many years as a trial statistician and leading a team of trial statisticians and therefore have experience of input to more than 100 trials. She also sits on 10 DMC or TSC at any one time. The majority of the trials are in cancer but latterly she has been involved in a broader range of illnesses. Recently, she has moved into a trial conduct role, aiming to evidence base and disseminate information about trial conduct. The trial conduct themes include monitoring, use of electronic health records in trials, improving the implementation of novel designs, increasing publication of trial experiences and data sharing. Last year, she and her colleagues published the TEMPER trial looking at the effectiveness of triggers in monitoring.



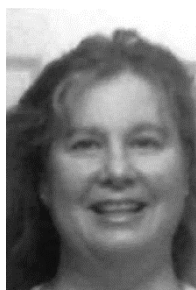
Mark McClellan is the Robert J. Margolis Professor of Business, Medicine, and Health Policy, and founding Director of the Duke-Margolis Center for Health Policy at Duke University. With offices in Durham, NC and Washington, DC, the Duke-Margolis Center is a university-wide, interdisciplinary initiative that is nationally and internationally recognized for its research, evaluation, implementation, and educational initiatives to improve health and health policy. The Center integrates Duke's expertise in the social, clinical, and analytical sciences with health care leader and stakeholder engagement to develop and apply policy solutions that improve health and the value of health care locally, nationally, and worldwide. Dr. McClellan is a physician and an economist who has informed and improved a wide range of strategies and policy reforms to advance health care, including payment reform to promote better outcomes and lower costs, methods for development and use of real-world evidence, and strategies for more effective biomedical innovation. Before coming to Duke, he served as a Senior Fellow in Economic Studies at the Brookings Institution, where he was Director of the Health Care Innovation and Value Initiatives and led the Richard Merkin Initiative on Payment Reform and Clinical Leadership. With highly distinguished record in public service and academic research, Dr. McClellan is a former administrator of the Centers for Medicare & Medicaid Services and former commissioner of the U.S. Food and Drug Administration (FDA), where he developed and implemented major reforms in health policy. These reforms include the Medicare prescription drug benefit, Medicare and Medicaid payment reforms, the FDA's Critical Path Initiative, and public-private initiatives to develop better information on the quality and cost of care. He previously served as a member of the President's Council of Economic Advisers, senior director for health care policy at the White House, and Deputy Assistant Secretary for Economic Policy at the Department of the Treasury. Dr. McClellan is the founding chair and a current board member of the Reagan-Udall Foundation for the FDA and a member of the National Academy of Medicine (NAM), where he chairs the Leadership Council for Value and Science-Driven Health care, co-chairs the guiding committee of the Health Care Payment Learning and Action Network, and is a research associate at the National Bureau of Economic Research. He is also a Senior Advisor on the faculty of the University of Texas Dell Medical School and co-chair of the Accountable Care Learning Collaborative. Dr. McClellan is an independent director on the boards of Johnson & Johnson, Cigna, and Alignment Healthcare. He was previously an associate professor of economics and medicine with tenure at Stanford University, and has twice received the Kenneth Arrow Award for Outstanding Research in Health Economics.



Ann Meeker-O'Connell is the Global Head, Quality Assurance at IQVIA. Ann has more than 20 years of clinical and biomedical research experience, including Quality Assurance leadership roles at the U.S Food & Drug Administration as the Director of the Division of Good Clinical Practice Compliance, as well as at Johnson & Johnson, Amgen and Pfizer. She is a recognized industry thought leader for clinical quality, having developed key FDA guidance related to trial oversight and led cross-industry innovation initiatives on clinical Quality by Design and Clinical Quality Management Systems. Ann also serves on the Board of Directors for the Association for the Accreditation of Human Research Protection Programs. Prior to joining IQVIA, Ann served at the Global Head of Consumer BioResearch Quality and Compliance (BRQC) at Johnson & Johnson. Ann began her career in pharmaceutical development designing clinical trials and providing operational study oversight for the National Cancer Institute. Ann holds a bachelor's degree in Biological Anthropology and Anatomy and a master's degree in Pharmacology from Duke University, where she was a Howard Hughes Fellow at the Duke Comprehensive Cancer Center and an NIH Integrated Toxicology fellow. She also holds certifications as an ISO 31000 risk management professional and trainer.



Camelia Mihaescu has almost 15 years of experience working in academia, the pharmaceutical industry and in a regulatory agency, in the fields of regulatory affairs, pharmacovigilance and clinical trials. She is a pharmacist by education and has been working at the European Medicines Agency for almost 5 years in the Committees and Inspections Department-Clinical and Non-Clinical Compliance Office. In her role Camelia is responsible for the coordination of GCP and pharmacovigilance inspections, taking part in drafting EU guidelines related to GCP and collaborating with international regulatory agencies on inspectional matters. Camelia has a PhD in Pharmaceutical Sciences.



Rosanne Petros is a Clinical Research Manager with Merck. She has been working in clinical research for 31 years in primarily project management and study operations roles. She has been speaking on risk-based monitoring and risk-based operational oversight for the past 6 years.



Tim Rolfe has over 20 years of experience working as a statistician at in the pharmaceutical industry. He is currently Director of Risk Based Monitoring at GlaxoSmithKline R&D. He has been part of GSKs RBM team since 2013, providing statistical leadership in the development and implementation of GSK's RBM strategy within clinical trials, including Risk Assessment, SDV/SDR sampling, Centralized Monitoring and QTLs. Tim also sits on the TransCelerate RBM Metrics workstream. Before joining GSK, Tim studied Applied Statistics at Sheffield Hallam University and holds a MSc in Medical Statistics from the University of Leicester in the UK.



Ty Rorick was named Interim Head of Research Operations in 2019. In this role, he leads all DCRI operations in support of clinical trials and studies, has leadership of the Operations Management Team, and oversees the DCRI's operational improvement initiatives. Previously, Rorick was Interim Director of the DCRI Industry Trials group. Before that, he spent 11 years in the DCRI MegaTrials group, rising from a project lead to an associate director; this followed 13 years with Procter & Gamble Pharmaceuticals. Rorick's work has spanned high-profile pivotal Phase III trials on behalf of the industry's leading pharmaceutical companies, to Phase I and II trials that require precise execution and deadline adherence. Rorick believes that building responsive, meaningful relationships are paramount to successful trials. His network of collaborations extends to the major clinical and academic research organizations of the world, mid-size to start-up biopharmaceutical companies, and institutes like the Patient-Centered Outcomes Research Institute (PCORI). He is deeply respected in the industry for his knowledge and clinical research management experience. Rorick holds a degree in business from the University of Cincinnati, and a nursing degree from Northern Kentucky University.



Nicole Stansbury, Vice President, Central Monitoring Services, joined Syneos Health in February 2019. Nicole has 26 years of experience in the industry beginning as a study coordinator in a multi-therapeutic site followed by 21 years at a large, global CRO where she spent several years as a Clinical Research Associate (CRA) and Project Manager (PM) before moving into leadership roles. Nicole's leadership roles included Head of Clinical Management in the Central US where she oversaw Clinical Team Managers (CTMs), CRAs and administrative staff and Head of Global Clinical Performance, a group responsible for clinical metrics, systems, process and quality where Nicole led the development of the risk-based monitoring (RBM) strategy, process and tools. Nicole has consulted with biotech companies on ICH E6 R2 compliance, conducted risk management training, performed a detailed assessments of EDC, CTMS, RBM and eTMF technologies for a small CRO and completed a risk management and centralized monitoring process assessment for a large pharmaceutical company. Nicole has a yellow belt in Lean Six Sigma, completed a Global Leadership program, received the 2011 CEO Leadership Excellence Award, met with the FDA in 2014 to share RBM strategy ideas, participated on ACRO's RBM Forum, presented at numerous industry conferences on RBM and published several articles on RBM and Change Management. Nicole has a B.S. in Animal Science from Texas A&M University.



Justin Stark is an Innovation Director within Global Development Operations (GDO) at Novartis. He has 10 years of clinical development operations experience. Prior to joining Novartis he has previously worked as Head of Risk Based Monitoring & Standards at UCB and Senior Director of Product Development at IQVIA (formerly Quintiles) with 7+ years developing and enhancing Risk Based Monitoring (RBM) capabilities. He has also been involved with the TransCelerate RBM workstream during his time at Novartis and UCB and served as a co-lead of TransCelerate's RBM Implementation Facilitation Team (RIFT) during his time at UCB. He received his MBA from Duke University and has a B.A. in economics from Harvard. Prior to pursuing his MBA and joining Quintiles, he had worked as a Six Sigma Black Belt. He and his family reside in Chapel Hill, North Carolina.



Linda Sullivan is Co-Founder & Executive Director of the Metrics Champion Consortium (MCC), an industry consortium dedicated to bringing clinical research sponsors, vendors and investigative sites together to collaboratively develop standardized performance metrics that help organizations oversee and manage studies, identify areas in need of improvement and assess process improvement activities. She has more than 30 years of experience working in the Healthcare and Clinical Research industries helping organizations improve processes to improve financial and quality outcomes. She has been a featured speaker at Performance

Metrics, Risk-Based Monitoring, Quality Management & Clinical Trial Oversight industry meetings, published articles in leading journals and served on industry advisory boards such as the NIH-NCATS Methods and Process Domain Task Force and the ACRP CRA Competency Steering Committee. Ms. Sullivan received a B.S. in Biology from Trinity College and a M.B.A. from Dartmouth College where she was named a Tuck Scholar.



Reb Tayyabkhan is currently the Head of Research & Global Development Sourcing at Regeneron, leading a team of Sourcing and Procurement professionals that support research labs, toxicology, genetics, clinical, regulatory and medical affairs. Prior to joining Regeneron in 2018, Reb spent 15 years at Bristol Myers Squibb leading a variety of Global Clinical Operations functions including Data Management, Regional Clinical Operations and Vendor & Outsourcing Management. Reb previously worked as a management consultant at PwC and a manufacturing engineer at Merck. Reb has also been an active member within TransCelerate Biopharma serving in multiple capacities including the leadership of the RBM team and as the liaison to the CRO Forum. Reb holds a Bachelors in Chemistry from NYU, a Masters in Chemical Engineering from Cornell and a MBA from NYU Stern.



Michael Walega is the Head of Centralized Monitoring at BMS. In this capacity, he is responsible for providing protocol teams with actionable insights to achieve higher quality, ensure that monitoring processes are aligned to ICH E6 (R2), and championing risk-based approaches to clinical trial monitoring activities. He was previously at Covance, where he led the team responsible for development and growth of Covance's Risk-Based Monitoring (RBM) solutions, processes, and operational delivery. Additionally, he also led the Late Stage Biostatistics and Programming groups, as well as the Process Excellence team. Mike is a qualified Biostatistician and a Six Sigma

Master Black Belt.



Steve Young, Chief Operations Officer for CluePoints, is primarily responsible for ensuring successful customer adoption of the CluePoints platform. Steve worked for three bio-pharmaceutical companies over a span of 15 years where he assumed leadership positions in clinical data management and led the successful enterprise roll-out of EDC at both J&J and Centocor. He spent an additional 6 years with eClinical solution providers Medidata and then OmniComm, leading the development of analytics and risk-based quality management (RBQM) solution portfolios and providing RBQM and clinical operations methodology consulting to many organizations. Steve also led a pivotal RBM-related analysis in collaboration with TransCelerate, and is currently leading RBQM best-practice initiatives for several industry RBM consortiums. Steve has co-authored two patents related to RBM methods. He holds a Master's degree in Mathematics from Villanova University.

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